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## Biotechnology

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**Report Highlights:**

There are signs of progress in the field of biotechnology in crop production in Germany. A noticeably increasing number of farmers is showing interest in planting Bt corn varieties. The planting area for Bt corn in 2007 is estimated at about 2500 ha versus 950 hectares in 2006. On the other side, NGOs and many politicians are fighting a desperate battle against the technology. Many politicians claim that research is ok but commercialization is not needed and not wanted. Amendments are being considered to the current German law governing field releases of biotech events and labeling of biotech foods

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## Section I: Executive Summary

An increasing number of German farmers are expressing interest in planting Bt corn varieties since they have a problem with the corn borer and the biotech industry offers them a solution with a wide range of advantages. In 2007, about 2,700 hectares were planted to Bt corn, which is an increase of about 1,600 hectares over 2006. However, research, production, and consumption of plants and plant products resulting from genetic enhancement of crops are still controversial issues in Germany. The scientific community and members of the conservative political parties have been generally supportive of biotechnology. However, they are counter-balanced by the Green Party, the Social Democrats and environment/consumer-related NGOs, which are very proactive and vocal in expressing their concerns about this technology.

Biotech opponents and skeptics continue to refer to consumer opinion polls, which show that about 70 to 80 percent of the German population are concerned about perceived risks resulting from the planting and consumption of biotech crops. Interestingly consumers predominantly refer to health risks while organized opponents prefer to refer to environmental risks resulting from the release to the environment. Small farmers associations claim that coexistence of biotech crops and non-biotech crops is impossible. In contrast, advantages resulting from biotech crops are unfortunately not yet well known among the majority of farmers.

The political and the industry focus is currently on intensifying efforts in the field of white biotechnology (basically the use of organic matter such as enzymes, bacteria, and plant tissue for industrial purposes, excluding open field planting), providing opportunities in the field of environmental protection, cost reducing chemical processes, improved utilization of available limited resources, and waste reduction. In Germany, white biotechnology is perceived positively, in part because Germans believe it does not create unmanageable risks. Another field of interest to the German biotech industry could be the production of renewable fuels and other products for non-food use. The industry perceives that such products will receive a higher level of acceptance since they do not enter the food chain.

In Germany, the regulatory framework for biotech products is set by EU regulations and directives (see GAIN report E35091), which in their current form are generally supported by the majority of German politicians. The European Commission however decided that co-existence rules would be determined and set by the individual Member States. Currently the German government is in the process of amending its genetech law to make it marginally more user-friendly and to define good management practices for biotech crops. An amendment of the long disputed liability regulations is not foreseen in the current draft version.

Currently, there are hardly any biotech-labeled food products found on German retail shelves. The retail business refrains from stocking biotech labeled products because they fear that anti-biotech activists may demonstrate in or outside their stores. Consolidation and competition in the German retail market is very intense and the prime marketing tool for the retailers is price. Since profit margins are very narrow in Germany, retailers try to avoid having any negative impressions of their products in the market.

## Section II: Biotechnology Trade and Production

### Commercial Production of Bt corn in Germany

Despite political opposition from the Green Party and to a somewhat lesser extend by the Social Democrats Party and lack of support by leading German farmers associations, about

70 farmers planted an estimated 2,700 hectares (3770 acres) of biotech corn varieties on a commercial basis in 2007. With almost three times as much area as in 2006, there is growing interest in the technology by German farmers. Originally at the beginning of 2007, farmers had registered about 3,250 hectares for Bt corn planting. Farmers registered more area for biotech production in order to maintain some flexibility until the actual planting takes place. When the planting work has been finished they have to report the actually planted fields to the field register.

Currently the only commercial biotech crop in Germany is corn and the only biotech trait approved for production is insect tolerance. Not all of the German corn production regions are affected by European corn borer infestation and the root worm has not yet arrived on German farm land. Current farmers' interest in Bt corn planting is predominantly in regions with large farm sizes, mainly in the eastern third of the country. Farmers in Southwest Germany are reportedly less interested in Bt varieties since that region is also a major corn seed production area and these farmers wish to ensure that their corn seeds are free of biotech presence.

Since 2003, genetech varieties in Germany have been using the biotech trait MON810. Previously, varieties containing the trait Bt176 were used. Since 2005, five corn varieties have been registered with the German Federal Seeds Register and may be planted to an unlimited area.

In 2004, an extensive coexistence research program accompanied the planting of about 300 hectares of Bt corn. The goal of this monitoring program, sponsored by federal research and state funds, was to determine the extent of the flow of corn pollen into neighboring fields. The industry intended to prove that biotech corn does not create a considerable problem for coexistence with non-biotech varieties. The result of the tests showed that biotech content in corn samples taken more than 20 meters from the biotech plants were below 0.9 percent, the threshold which constitutes the need for labeling the harvested product as biotech. See also [http://www.transgen.de/pdf/erprobungsanbau/ergebnisse\\_sonderdruck.pdf](http://www.transgen.de/pdf/erprobungsanbau/ergebnisse_sonderdruck.pdf)

To avoid any kind of liability problems for the production of biotech corn in 2005 and 2006, the German feed milling and grain trading company Maerka Kraftfutter made the public promise to purchase the corn from fields neighboring biotech corn fields up to a distance of 500 meters. The purchase price will be equivalent to normal market prices in the region, regardless of biotech content. Maerka also markets and processes domestically harvested biotech corn into commercial feed compounds and labels these products as 'contains biotech corn'.

### **Research on Biotech Crops**

In Germany research on biotech crops concentrates primarily on potatoes. However field releases are also approved for corn, peas, winter wheat, winter barley, rapeseed, apples and soybeans. A list of these approved field trial releases is found on following web page:

[http://www.bvl-berlin.de/cgi/lasso/fsl/liste\\_d.lasso?-database=SNIF&-response=&-table=www\\_summary&-sortField=Aktenzeichen%20RKI&-sortOrder=ascending&-op=bw&land=Deutschland&-maxRecords=20&-search&-skiprecords=120](http://www.bvl-berlin.de/cgi/lasso/fsl/liste_d.lasso?-database=SNIF&-response=&-table=www_summary&-sortField=Aktenzeichen%20RKI&-sortOrder=ascending&-op=bw&land=Deutschland&-maxRecords=20&-search&-skiprecords=120)

Field releases for corn are mainly for the testing of stacked trait varieties. Research on potatoes covers a variety of issues, such as altering the starch composition and fungus resistance.

Applications for field releases during the past several years concentrated on potatoes and corn. These are crops, which have a low out-crossing risk in terms of coexistence. The biotech industry has pretty much stopped or reduced field studies in Germany with higher out-crossing potential, such as rapeseed, which have the potential to create a major controversy with biotech opponents. Despite the efforts to promote consumer, processor, and environment friendly biotech traits, anti-biotech activists increasingly focus their destructive efforts on test fields.

### **Genetech-free Zones**

Aside from the commercial production and research areas for biotech crops, groups of German farmers have declared about 140 regions in Germany as biotech-free zones (93 regions in 2006). The total area covered by these biotech-free zones amounts to about 1.55 million hectares (861,000 hectares in 2006) with 27,500 participating farmers. A large number of these regions are located in Bavaria and are primarily composed of grassland for dairy production. These zones are formed by the voluntary agreement of farmers to not plant biotech crops in the particular region. In part these declarations are used for tourism purposes. Other non-biotech regions were initiated by organic farmers. There is no legal enforcement mechanism connected to this declaration that would prevent a farmer from growing biotech plants. Also the Christian churches are an active NGO opposing genetechology on church-owned land.

See: <http://www.gentechnikfreie-regionen.de/>

## **Section III: Biotechnology Policy**

Leadership for biotechnology policy in Germany rests with the Federal Ministry for Food, Agriculture and Consumer Protection (BMELV). However, the Ministries of Economics, Health, Research and Environment are also involved in the opinion and decision-making process and need to approve Germany's voting decision in EU committees and councils. This split of responsibility also applies to Germany's role in the Biosafety and Biodiversity committees. The German regulatory offices for biotech authorization and risk assessment are under the political leadership and supervision of BMELV.

The willingness to promote or at least tolerate the presence of biotech foods and feeds and the planting of biotech crops is highly dependent on the political leadership of BMELV. In many public statements, Minister Seehofer, BMELV, has expressed his support for intensified research on green biotech but is still extremely reluctant to also promote the planting of biotech crops.

### **Regulatory Framework**

The regulatory framework for biotechnology is set by EU regulations and directives. While regulations directly apply in all EU member countries, directives have to be transferred and incorporated into national laws. This incorporation process requires that national laws have to be crafted or existing laws need to be amended accordingly. Directives provide the opportunity for member countries to exercise some discretion and strengthen or weaken the EU requirement without altering the basic scope of the EU directive.

The German government took advantage of this discretion while crafting its national genetech law in 1998. In particular, rules about liability, coexistence, and a public register for fields planted to biotech crops were originally crafted in a way to discourage farmers and researcher from growing and developing biotech events in Germany.

Also, under separate regulations Germany allowed beginning in 1998 products to be labeled as "without genetechology". This label currently may be used for products derived from

conventional seed varieties and from animals, which were not fed with biotech containing feedstuffs. Also the use of biotech derived feed additives, enzymes and medicine is not permitted. A specific threshold level for adventitious and unavoidable presence of biotech is not established in the regulation. The 'without genetech' label has not been used often during the past eight years. Additionally, the 'without genetech' label may not be used for products, for which no varieties have yet been genetically engineered worldwide, such as oranges or basmati rice among others.

### German Industry Concerns and Requests

The German biotech industry and plant breeders have expressed strong concern for a number of years about the current regulations. The industry has requested to change the access procedures to the **biotech field register**. The current version of the register is accessible to everyone through the internet. The industry would like some oversight to ensure that access to the register is not being used to implement field destructions. It was proposed that the information for the general public should only reveal information about the sub-local district where the field is located.

Another point of clarification that the industry has sought was the **liability regulation**. The industry requested that only the mercantile depreciation of the harvested crop, which got in touch with biotech traits, should be the basis for a possible compensation claim. Additionally, private contracts detailing that an organic crop is completely free of biotech traces should not qualify for compensation demands.

### Proposed Changes in the German Genetech and Labeling Laws

Despite the change in the German government in November 2005 from a Social Democrats (SPD) and Green Party coalition to a more business oriented and more conservative coalition of the Christian Democrats and the Social Democrats, the opposition in the general public and among the majority of parliamentarians against biotechnology in plant production has not changed noticeably. Many of the SPD parliamentarians are now taking the position of the Green party and strongly oppose biotechnology in crop production using 'Green' arguments. The base argument is that biotech crops are not sufficiently researched and that they might cause a hazard to the environment once released.

However, the 2005 coalition contract between the Christian Democrats Party and the Social Democrats states that the new government is generally supportive of research in biotechnology and wishes to guarantee fair opportunities for the production of conventional, organic, and biotech seeds. To implement this pledge the German government released a strategy paper in February 2007 for an amendment to the German Genetech law. The paper stated that it is the intent of the government to promote research and commercialization of biotech crops. This paper discussed several areas where amendments might be considered to the current genetech law including: coexistence, liability and the field register. After substantial interagency discussion, a compromise proposal was sent to the German Bundestag which, if pass and implemented, will only marginally improve the prospects for introducing biotech events in Germany.

The most controversial portion of the proposed rules is the required minimum distance between biotech fields and fields planted to conventional or organic varieties. The intended protection distance is proposed at 150 meters to conventional corn varieties and 300 meters to organic corn. The draft regulation also proposes some flexibility if neighboring farmers agree on shorter distances. The option for coverseeds as an alternative for the distance requirement is not foreseen in the current draft regulation. BMELV claims that such cover plantings are not effective.

The coalition compromise for the genetechnology law amendment foresees that the existing high level of transparency of the biotech field register will remain in place despite an increasing number of field destructions. Also the strict liability rules are not intended to be made more practical for farmers and researchers.

Parliamentary action on these proposed amendments is expected later in 2007.

Separately, Minister Seehofer has proposed an amendment of the 'without genetechnology' labeling law to ease the conditions for the use of the 'without genetechnology' label on food and feed stuffs. As with the current regulation, food and feedstuffs, including milk and dairy products, eggs and meat and processed products containing such ingredients, could apply this label if the ingredients originate from animals, which were fed with non-biotech feeds. However, the new 'without genetechnology' labeling proposal, unlike the current regulation, would allow the use of feed additives and enzymes and medicine derived from biotechnology. With this move the government intends to counter growing criticism that animals fed with biotech crops do not need to be labeled as biotech livestock products. It is argued that the eased 'without genetechnology' label would provide the consumer with an improved option to choose. Some agricultural industry groups have challenged this proposal indicating that it will likely confuse consumers rather than help in making informed choices.

#### **Antibiotic Resistance Marker Genes**

The biotech trait Bt176, has been banned for use as a seed in Germany. The German government argues that the presence of an antibiotic resistance marker gene in Bt176 has the potential to pose a threat to public health and to the environment. Although the German research community disagrees with this negative evaluation, Germany voted in Brussels against lifting the ban for Bt176.

#### **Biotech Threshold levels**

The EU labeling directive sets a labeling threshold for unavoidable adventitious presence of EU-approved biotech events in food and feed at 0.9 percent. This also applies to organic products. A threshold level for adventitious biotech content in seeds has not yet been set, which actually translates into a zero tolerance for biotech content in conventional or organic seeds. The German government has not developed a position about their preferred biotech threshold level. The biotech strategy paper of February 2007 says that it should be as low as possible but still practical for the seeds industry. A number has not been mentioned.

If traces of EU approved biotech events are found in seeds, these seeds need to be labeled as containing biotech or these seeds cannot be marketed. According to EU rules, also fields adventitiously planted with these seeds need to be recorded in the biotech field register. Since this is not possible because the farmer normally does not know about the adventitious biotech presence in his seeds the regional supervising authorities usually require that these crops be destroyed. Not yet EU approved biotech events are totally prohibited in seeds.

#### **Section IV: Marketing Issues**

Biotechnology in crop production is a highly contentious issue in Germany as in most other EU countries. Opinion polls provide widely varying results. Opponents to biotechnology often point to polling results that show that about 70 percent of the German population is in opposition to this technology. Other polls, if questions are asked differently, come to the



result that about 83 percent of the people interviewed did not see any problem in biotech-labeled products being on food retail shelves.

Recent polls amongst farmers in northern and eastern Germany revealed that farmers operating large farms are quite interested in using the new technology. In Mecklenburg-Vorpommern, a northeastern German state, 35 percent of the questioned farmers said that they would consider planting biotech crops, 43 percent rejected the idea and 19 percent were undecided. About 47 percent of the farmers operating farms of more than 1,000 hectares (2,500 acres) support the technology. Interestingly, 48 percent of the farmers expect that biotech varieties will be the future in plant breeding. Only 22 percent believe that biotech crops will not succeed.

Since the implementation of EU labeling regulations for biotech foods in April 2004, an NGO reportedly found a number of food items on the German retail shelves containing biotech or biotech-derived products, which in most cases were incorrectly labeled. Activists have also visited restaurants and take-away food places where they found biotech soyoil, which was not labeled on the menu. The activists 'convinced' the restaurant owners and the retailers to switch to other non-biotech products or take the products off the shelf. The products found were imported candy bars containing biotech cornstarch and soybean products, such as soyoil, tofu, and bean sprouts.

To avoid biotech labeling of processed food items, the German food industry switched from biotech-origin ingredients to non-biotech alternatives. This substitution was most prevalent for soybean oil, which was replaced with European rapeseed oil. Because of rising demand for rapeseed oil in biodiesel production, rapeseed oil has become the most expensive vegetable oil in the EU. Even sunflower oil is lower priced than rapeseed oil. Due to the relatively high cost for rapeseed oil, the domestic food processing industry has begun to reconsider whether they should return to use lower-priced soybean oil, which would require a biotech label. However, such a step needs to be carefully researched and negotiated with the retail sector.

Food sales in Germany are predominantly driven by price. As a result, generic products, which are generally more affordable, are increasingly replacing branded products. In view of this intense competition, retail companies wish to avoid placing biotech labeled products on their shelves.

### **Unapproved Biotech Events**

On several occasions in the past years, unauthorized biotech products had been detected on the German retail market and at the ports of entry. Most notable papayas, longgrain rice and corn gluten feed. Competent authorities forced the importer of the papayas to destroy these products, which came from genetically modified plants that were bred to be disease resistant. Since January 2005, all incoming papaya shipments from Hawaii must be tested for biotech presence before they can be marketed. The rice containing marginal traces of an unapproved biotech trait had to be taken from the shelf. This action cost the involved rice mills millions of Euros although the European food safety authorities had frequently confirmed that the rice is safe for human consumption. Domestic rice millers have switched to alternative suppliers from Uruguay, Thailand and other countries. However, the rice millers have indicated an interest in returning to the U.S. rice market when they have the assurance that the imported rice meets EU approval.

The presence of traces of the biotech event Herculex RW in corn gluten feed (CGF) is also causing problems for German / European feed importers. German feed processors complain that they cannot obtain any CGF or distillers dried grain (DDG) from ethanol production in



the United States, which reportedly sells at significantly lower prices than European feed grains. International traders seem to hesitate to take the risk to handle corn based feeds, which might contain traces of not yet approved biotech events.

### **Testing for Biotech Events**

Germany has a decentralized system for testing and controlling the illegal entry of biotech products into Germany. The control authority with the competence to ensure that no unauthorized biotech product enters the German retail market is with the 16 German states (Laender). The Laender establish their own monitoring and sampling plans. Since the experts know what kind of products potentially contain biotech events they specifically sample for these products. Sampling is primarily done at the wholesale and the processing level.

### **NGO Activities**

The German green-based NGOs have undertaken intensive efforts to keep biotech crops out of the fields and biotech food products off the shelves. NGOs met with German food processors and retailers to request commitments to keep their retail shelves and production plants biotech-free. Reportedly the majority of food processors did not sign such commitments. Companies committing themselves to avoid biotech are predominantly those dealing with organic products. Since the German food processing industry has replaced biotech ingredients with other non-biotech products, such as EU rapeseed oil, NGOs have recently been focusing on the dairy industry. NGOs would like to obtain commitments from the dairy companies that they will require their supplying farmers not to use biotech containing feeds. To ensure that small restaurant and catering places are not using biotech vegetable oil NGOs send around biotech scouts requesting information from the restaurants what kind of vegetable oils they are using.

Due to the long list of field destructions the seeds and biotech industry as well as research institutes lost their patience with the 'activists' and now take them to court with the intent to claim financial compensation for the complete damage, not only the value of the lost crop. Damages can easily add up to several million dollars.

The most recent biotech discrediting approach of NGOs is a study where they took samples from many different corn plants off the fields and tested them for the concentration level of the *Bacillus thuringiensis* toxin. The finding that the toxin level can vary significantly from plant to plant is used as an argument that a targeted application against the corn borer is not possible. Reports like this are welcome by the community of biotech opponents.

Another venue of biotech criticism are recent legal claims of beekeepers against biotech farmers claiming that biotech corn contaminates the honey and makes the honey a biotech product which is not approved in the EU. Final court rulings are still outstanding.

Field destructions increasingly focus on research plots and variety tests. Opponents are aware that these actions can have great impact on the future of biotech crop development in Europe. In 2006, 26 field destructions were recorded in Germany. This compares to only 7 cases in 2005. During the short 2007 field season, already two fields have been destroyed and demonstrations have been announced for mid July.

Christian churches have taken a strong position against biotechnology in plant production. This results in the condition in land rental contracts the operating farmers commits himself not to grow any biotech crops on church owned land or to refrain totally from biotech crops if only part of his land is rented from the churches.

**Cultivation Restriction for MON810 corn**

In late April 2007, BVL released an order against Monsanto to ban the sales of MON810 corn variety seeds until Monsanto provides an extended plan detailing how potential environmental impacts are to be monitored. The order claims that new information or new interpretation of existing material justified cause for the implementation of an extended monitoring plan focusing on potential impact on the environment. To date no final monitoring plan for MON810 has been accepted by BVL and it is unclear what the impact for the 2008 planting will be.

The order sends out a signal to the biotech skeptics that there might be something problematic with the new seeds and more research is needed before biotech crops can be planted. Interestingly, the German competent authority Bundesamt fuer Risikobewertung (Federal Office for Risk Assessment) came to the result that none of the studies referenced in the order have proven that MON810 has potential for being harmful to the environment.

**Section V: Capacity Building and Outreach****Informational Visits to the U.S. and Speaker Programs**

Since 1997, the FAS Office in Germany has sent numerous groups of policy makers, scientists, representatives of consumer organizations, farm leaders, journalists and other interested parties to the United States to learn about the U.S. system for regulating gene technology.

In addition to these trips to the United States, FAS Germany has organized a number of speaker programs for U.S. biotech scientists and farmers to inform interested parties in Germany about the experience in the U.S. with biotech crops. The Agricultural Minister Counselor of the FAS Office in Germany participated in a number of podium discussions and seminars on biotechnology.

Most helpful for the success of biotech crops in Germany appears to be farmer to farmer contacts on national and international levels. On June 16, 2006, 23 farmers from Northern Germany formed a Working Group of Innovative Farmers (InnoPlanta AGIL) – [www.innoplanta.de](http://www.innoplanta.de). These farmers are convinced that this technology will be a key technology of the 21<sup>st</sup> century and play a growing role in world food production, renewables development, energy, health, and environment. Most welcome for German farmers is also the exchange of experience with knowledgeable North American farmers because this tells them that there are not only the promises of the offering seed companies but also the positive results for the farmers and the environment.

**White Biotechnology**

During the past year, politicians of almost all leading German political parties expressed their support for white biotechnology. Even the Green Party claims that this is a field of research and development, which provides great opportunities to the German economy without expressing noticeable risk to the environment and to health. As a result, this branch of the German biotech industry seems to be faring better than green biotechnology.

**Biotech Varieties for Energy Crops**

The recent rise in commodity prices have generated second thoughts about the 'need' for biotech varieties. It is frequently heard that the application of biotech crops in the production of crops for industrial uses such as biofuels could be tolerated. However, this discussion is still at initial stages.

**Section VI : Reference Material**

Report No.	Date	Title
GM7033	07/27/2007	Biotech Law Coalition Compromise
GM7017	03/30/2007	Green Party Campaign against Biotech
GM7012	03/16/2007	Lawsuit against Biotech Wheat Field Test
GM7010	03/16/2007	Green Party Steps up Anti-Biotech Rhetoric
GM7008	03/07/2007	Proposal for German Genetech Law Amendment
GM7006	02/16/2007	Biotech Corn Planting Intentions for 2007
GM7003	01/23/2007	Biotech Outreach to Germany
GM6047	12/05/2006	German Genetech Law Amendment Proposal
GM6046	11/28/2006	Biotech Wheat Field Test Approved
GM6042	11/07/2006	Biotech Situation
GM6032	08/25/2006	LLRice601 Reaction in Germany
GM6021	06/26/2006	Biotech Annual